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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,287

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,287	Applicant(s) FUTERMAN ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 123-159 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 123-159 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 123-159 are pending in the application.
- [2] Applicant's preliminary amendment to the claims, filed on 10/4/05, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims. Claims 1-122 have been canceled and claims 123-159 have been added relative to the original claim listing.
- [3] Applicant's preliminary amendment to the specification, filed on 10/4/05, is acknowledged.
- [4] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 1/4/07, is acknowledged. *In order to perfect compliance with the rules for a sequence listing, applicant is required to submit a formal amendment to the specification, directing entry of the substitute sequence listing paper copy into the specification.*
- [5] Receipt of a substitute Declaration under 37 CFR 1.63, filed on 1/4/07, is acknowledged.
- [6] Receipt of an information disclosure statement, filed on 6/27/07, is acknowledged.

Lack of Unity

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[7] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 123-141, drawn to the special technical feature of a composition-of-matter comprising a crystallized glucocerebrosidase, a method of crystallizing a glucocerebrosidase molecule, a glucocerebrosidase preparation, a pharmaceutical composition, and an article of manufacture.

Group II, claim(s) 142-152, drawn to the special technical feature of a method of producing a glucocerebrosidase preparation.

Group III, claim(s) 153, drawn to the special technical feature of a method of increasing glucocerebrosidase activity in a cell.

Group IV, claim(s) 154-155, drawn to the special technical feature of a method of treating a disease.

Group V, claim(s) 156, drawn to the special technical feature of a method of identifying a compound.

Group VI, claim(s) 157-158, drawn to the special technical feature of a computing platform and a computer-readable medium.

Group VII, claim(s) 159, drawn to the special technical feature of a computer generated model.

If applicant elects the invention of Group I, applicant is further required under PCT Rule 13.1 to elect a single glucocerebrosidase from the following:

- a) glucocerebrosidase of Table 4 and SEQ ID NO:1
- b) glucocerebrosidase of Table 5
- c) glucocerebrosidase of Table 6
- d) glucocerebrosidase of Table 7
- e) glucocerebrosidase of Table 8
- f) glucocerebrosidase of Table 9
- g) glucocerebrosidase of Table 10

- h) glucocerebrosidase of SEQ ID NO:8
- i) glucocerebrosidase of SEQ ID NO:16

If applicant elects the invention of Group II, applicant is further required under PCT Rule 13.1 to elect a single glucocerebrosidase from the following:

- j) SEQ ID NO:1 k) SEQ ID NO:8
- l) SEQ ID NO:16

If applicant elects the invention of Group I or II, applicant is further required under PCT Rule 13.1 to elect a single glycosylation residue from the following:

- m) glycosylation residue 1, Asn19
- n) glycosylation residue 2, Asn59
- o) glycosylation residue 3, Asn146
- p) glycosylation residue 4, Asn270

[8] The technical feature linking groups I-VII is a crystallized glucocerebrosidase molecule. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VII is a glucocerebrosidase polypeptide. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure, which is a significant structural element. Although the glucocerebrosidase polypeptides of SEQ ID NO:1, 8, and 16, the structural coordinates of Tables 4-10, and glycosylation sites 1, 2, 3, and 4 share a common structure, the

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polypeptides, structural coordinates, or glycosylation sites are not regarded as being of similar nature because the shared common structure is not a significant structural element.

According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The crystal of Group I, the method of Group II, the method of Group V, the computing platform of Group VI, and the computer model of Group VII share no special technical feature as the crystal of Group I encompasses glucocerebrosidase polypeptides having structures that do not correspond to the method of Group II, the structural coordinates of the computing platform of Group VI, and the computer model of Group VII.

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-VII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a crystal of a glucocerebrosidase, which is shown by Roeber et al. (*Acta Crystallogr D Biol Crystallogr* 59:343-344, 2003; cited in the IDS filed on 6/27/07, reference 3) to lack novelty or inventive step because the reference of Roeber et al. teaches a crystal of glucocerebrosidase and does not make it a contribution over the prior art.

37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Group IV does not have unity of invention with the polypeptide of Group I.

[9] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[10] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[11] The claims will be examined only to the extent they read on the elected subject matter.

Notice of Possible Rejoinder

[12] The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting

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rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
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